AMENDED IN ASSEMBLY AUGUST 24, 2006

AMENDED IN ASSEMBLY AUGUST 21, 2006

AMENDED IN ASSEMBLY AUGUST 7, 2006

AMENDED IN ASSEMBLY JUNE 29, 2006

AMENDED IN ASSEMBLY JUNE 13, 2006

AMENDED IN SENATE MAY 1, 2006

AMENDED IN SENATE APRIL 6, 2006

AMENDED IN SENATE MARCH 27, 2006

SENATE BILL No. 1301

Introduced by Senator Alquist

February 16, 2006

An act to amend Section 1280.1 of, and to add Sections 1279.1, 1279.2, and 1279.3 to, the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, as amended, Alquist. Health facilities: reporting and inspection requirements.

Existing law provides for the inspection, licensure, and regulation of health care facilities by the State Department of Health Services, including, among other facilities, general acute care hospitals, acute psychiatric hospitals, special hospitals, and long-term health care facilities, some of which are collectively referred to as nursing homes. Existing law requires that all licensed general acute care hospitals maintain a medical records system, as specified, that organizes all

medical records for each patient under a unique identifier, and develop and implement policies and procedures to ensure that relevant portions of patients' medical records can be made available within a reasonable period of time to respond to the request of a treating physician, other authorized medical professionals, authorized representatives of the department, or any other person authorized by law to make such a request, taking into consideration the physical location of the records and hours of operation of the facility where those records are located, as well as the interests of the patients.

Existing law establishes licensing and certification fees applicable to various clinics, health care providers, and health facilities, health care providers, and health facilities, for the 2006–07 fiscal year, and requires the department, commencing February 1, 2007, and every February 1 thereafter, to publish a list of estimated fees, based on specified calculations and cost estimates. Existing law also requires the department, by February 1 of each year, among other reports, to prepare and make available to interested persons a staffing and systems analysis to ensure efficient and effective utilization of fees collected, proper allocation of departmental resources to licensing and certification activities, survey schedules, complaint investigations, enforcement and appeal activities, data collection and dissemination, surveyor training, and policy development, including specified information.

This bill would require that information on the number and timeliness of adverse event investigations related to reports of adverse events also be included in that analysis.

This bill would require the department to take various actions related to the reporting to, and the investigation by, the department of any adverse event, as defined, that occurs at a general acute care hospital, acute psychiatric hospital, or special hospital. The bill would require a general acute care hospital, acute psychiatric hospital, or special hospital to report to the department any adverse event, as defined, within 5 days of its discovery, unless the adverse event is an ongoing urgent or emergent threat to the welfare, safety, or health of patients, personnel, or visitors, in which case the event shall be reported to the department within 24 hours of its discovery. The bill would authorize the department to assess specified civil penalties against a licensee for failure to report an adverse event as required by the bill.

This bill would require the department to conduct an onsite inspection or investigation within 48 hours or 2 business days of a complaint that indicates an ongoing threat of imminent danger of death or serious bodily harm at a general acute care hospital, an acute psychiatric hospital, or a special hospital. The bill would require information about the reported adverse event and the outcome of investigations or inspections of substantiated adverse events reported conducted in accordance with these provisions to be posted on the department's Internet Web site and available in written form, by January 1, 2015. The bill would require the department to make this information readily accessible to consumers between January 1, 2009 and January 1, 2015. The bill would require the department to make related data available to entities deemed appropriate by the department, to be posted on the entities' Internet Web sites.

The bill would require the costs of administering and implementing certain of its provisions to be paid from funds derived from licensing fees paid by general acute care, acute psychiatric, and special hospitals.

This bill would make its provisions operative on July 1, 2007.

Violation of provisions relating to the operation of health facilities is a crime. Therefore, by imposing new and revised requirements on health facilities, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1279.1 is added to the Health and Safety Code, to read:

1279.1. (a) A health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250 shall report an adverse event to the department no later than five days after the adverse event has been detected, or, if that event is an ongoing urgent or emergent

threat to the welfare, health, or safety of patients, personnel, or visitors, not later than 24 hours after the adverse event has been detected. Disclosure of individually identifiable patient information shall be consistent with applicable law.

(b) For purposes of this section, "adverse event" includes any of the following:

(1) Surgical events, including the following:

(A) Surgery performed on a wrong body part that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery or a situation that is so urgent as to preclude obtaining informed consent.

(B) Surgery performed on the wrong patient.

(C) The wrong surgical procedure performed on a patient, which is a surgical procedure performed on a patient that is inconsistent with the documented informed consent for that patient. A reportable event under this subparagraph does not include a situation requiring prompt action that occurs in the course of surgery, or a situation that is so urgent as to preclude the obtaining of informed consent.

(D) Retention of a foreign object in a patient after surgery or other procedure, excluding objects intentionally implanted as part of a planned intervention and objects present prior to surgery that are intentionally retained.

(E) Death during or up to 24 hours after induction of anesthesia after surgery of a normal, healthy patient who has no organic, physiologic, biochemical, or psychiatric disturbance and for whom the pathologic processes for which the operation is to be performed are localized and do not entail a systemic disturbance.

(2) Product or device events, including the following:

(A) Patient death or serious disability associated with the use of a contaminated drug, device, or biologic provided by the health facility when the contamination is the result of generally detectable contaminants in the drug, device, or biologic, regardless of the source of the contamination or the product.

(B) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. For purposes of this

subparagraph, “device” includes, but is not limited to, a catheter, drain, or other specialized tube, infusion pump, or ventilator.

(C) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a facility, excluding deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.

(3) Patient protection events, including the following:

(A) An infant discharged to the wrong person.

(B) Patient death or serious disability associated with patient disappearance for more than four hours, excluding events involving adults who have competency or decisionmaking capacity.

(C) A patient suicide or attempted suicide resulting in serious disability while being cared for in a health facility due to patient actions after admission to the health facility, excluding deaths resulting from self-inflicted injuries that were the reason for admission to the health facility.

(4) Care management events, including the following:

(A) A patient death or serious disability associated with a medication error, including, but not limited to, an error involving the wrong drug, the wrong dose, the wrong patient, the wrong time, the wrong rate, the wrong preparation, or the wrong route of administration, excluding reasonable differences in clinical judgment on drug selection and dose.

(B) A patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products.

(C) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a facility, including events that occur within 42 days postdelivery and excluding deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.

(D) Patient death or serious disability directly related to hypoglycemia, the onset of which occurs while the patient is being cared for in a health facility.

(E) Death or serious disability, including kernicterus, associated with failure to identify and treat hyperbilirubinemia in neonates during the first 28 days of life. For purposes of this

subparagraph, "hyperbilirubinemia" means bilirubin levels greater than 30 milligrams per deciliter.

(F) A Stage 3 or 4 ulcer, acquired after admission to a health facility, excluding progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.

(G) A patient death or serious disability due to spinal manipulative therapy performed at the health facility.

(5) Environmental events, including the following:

(A) A patient death or serious disability associated with an electric shock while being cared for in a health facility, excluding events involving planned treatments, such as electric countershock.

(B) Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by a toxic substance.

(C) A patient death or serious disability associated with a burn incurred from any source while being cared for in a health facility.

(D) A patient death associated with a fall while being cared for in a health facility.

(E) A patient death or serious disability associated with the use of restraints or bedrails while being cared for in a health facility.

(6) Criminal events, including the following:

(A) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider.

(B) The abduction of a patient of any age.

(C) The sexual assault on a patient within or on the grounds of a health facility.

(D) The death or significant injury of a patient or staff member resulting from a physical assault that occurs within or on the grounds of a facility.

(7) An adverse event or series of adverse events that cause the death or serious disability of a patient, personnel, or visitor.

(c) The facility shall inform the patient or the party responsible for the patient of the adverse event by the time the report is made.

(d) "Serious disability" means a physical or mental impairment that substantially limits one or more of the major life activities of an individual, or the loss of bodily function, if the

impairment or loss lasts more than 7 days or is still present at the time of discharge from an inpatient health care facility, or the loss of a body part.

(e) Nothing in this section shall be interpreted to change or otherwise affect hospital reporting requirements regarding reportable diseases or unusual occurrences, as provided in Section 70737 of Title 22 of the California Code of Regulations. The department shall review Section 70737 of Title 22 of the California Code of Regulations requiring hospitals to report "unusual circumstances" and consider amending the section to enhance the clarity and specificity of this hospital reporting requirement.

SEC. 2. Section 1279.2 is added to the Health and Safety Code, to read:

1279.2. (a) (1) In any case in which the department receives a report from a facility pursuant to Section 1279.1, or a written or oral complaint involving a health facility licensed pursuant to subdivision (a), (b), or (f) of Section 1250, that indicates an ongoing threat of imminent danger of death or serious bodily harm, the department shall make an onsite inspection or investigation within 48 hours or two business days, whichever is greater, of the receipt of the report or complaint and shall complete that investigation within 45 days.

(2) Until the department has determined by onsite inspection that the adverse event has been resolved, the department shall, not less than once a year, conduct an unannounced inspection of any health facility that has reported an adverse event pursuant to Section 1279.1.

(b) In any case in which the department is able to determine from the information available to it that there is no threat of imminent danger of death or serious bodily harm to that patient or other patients, the department shall complete an investigation of the report within 45 days.

(c) The department shall notify the complainant and licensee in writing of the department's determination as a result of an inspection or report.

(d) For purposes of this section, "complaint" means any oral or written notice to the department, other than a report from the health facility, of an alleged violation of applicable requirements of state or federal law or an allegation of facts that might

constitute a violation of applicable requirements of state or federal law.

(e) The costs of administering and implementing this section shall be paid from funds derived from existing licensing fees paid by general acute care hospitals, acute psychiatric hospitals, and special hospitals.

(f) In enforcing this section and Sections 1279 and 1279.1, the department shall take into account the special circumstances of small and rural hospitals, as defined in Section 124840, in order to protect the quality of patient care in those hospitals.

(g) In preparing the staffing and systems analysis required pursuant to Section 1266, the department shall also report regarding the number and timeliness of investigations of adverse events initiated in response to reports of adverse events.

SEC. 3. Section 1279.3 is added to the Health and Safety Code, to read:

1279.3. (a) By January 1, 2015, the department shall provide information regarding reports of substantiated adverse events pursuant to Section 1279.1 and the outcomes of inspections and investigations conducted pursuant to Section 1279.1, on the department's Internet Web site and in written form in a manner that is readily accessible to consumers in all parts of California, and that protects patient confidentiality.

(b) By January 1, 2009, and until January 1, 2015, the department shall make information regarding reports of *substantiated* adverse events pursuant to Section 1279.1, and outcomes of inspections and investigations conducted pursuant to Section 1279.1, readily accessible to consumers throughout California. The department shall also compile and make available, to entities deemed appropriate by the department, data regarding these reports of *substantiated* adverse events *pursuant to Section 1279.1* and outcomes of inspections and investigations *conducted pursuant to Section 1279.1*, in order that these entities may post this data on their Internet Web sites. *Entities deemed appropriate by the department shall enter into a memorandum of understanding with the department that requires the inclusion of all data and all hospital information provided by the department.* These entities may include universities, consumer organizations, or health care quality organizations.

(c) The information required pursuant to this section shall include, but not be limited to, information regarding each substantiated adverse event, as defined in Section 1279.1, reported to the department, and may include compliance information history. The names of the health care professionals and health care workers shall not be included in the information released by the department to the public.

SEC. 4. Section 1280.1 of the Health and Safety Code is amended to read:

1280.1. (a) (1) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to correct a deficiency within the time specified in a plan of correction, the state department may assess the licensee a civil penalty in an amount not to exceed fifty dollars ($50) per patient affected by the deficiency for each day that the deficiency continues beyond the date specified for correction. The civil penalties shall be assessed only for deficiencies that pose an immediate and substantial hazard to the health or safety of patients. If the licensee disputes a determination by the state department regarding alleged failure to correct a deficiency or regarding the reasonableness of the proposed deadline for correction, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

(2) Paragraph (1) shall not apply to a deficiency for which a facility was cited prior to January 1, 1994.

(b) If a licensee of a health facility licensed under subdivision (a), (b), or (f) of Section 1250 fails to report an adverse event pursuant to Section 1279.1, the department may assess the licensee a civil penalty in an amount not to exceed one hundred dollars ($100) for each day that the adverse event is not reported following the initial five-day period or 24-hour period, as applicable, pursuant to subdivision (a) of Section 1279.1. If the licensee disputes a determination by the department regarding alleged failure to report an adverse event, the licensee may, within 10 days, request a hearing pursuant to Section 100171. Penalties shall be paid when appeals pursuant to those provisions have been exhausted.

SEC. 5. This act shall become operative on July 1, 2007.

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O